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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/758,304  | 01/14/2004  | Bruce W. Anderson    | GP106-10-CN2                    | 5359                        |
| 21365 7590 09/13/2007<br>GEN PROBE INCORPORATED<br>10210 GENETIC CENTER DRIVE<br>Mail Stop #1 / Patent Dept.<br>SAN DIEGO, CA 92121 |             |                      | EXAMINER<br>RAMDHANIE, BOBBY    |                             |
|   |             |                      | ART UNIT<br>1709                | PAPER NUMBER                |
|   |             |                      | NOTIFICATION DATE<br>09/13/2007 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdept@gen-probe.com  
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## Office Action Summary

**Application No.**

10/758,304

**Applicant(s)**

ANDERSON ET AL.

**Examiner**

Bobby Ramdhanie, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/14/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 01/24/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The non-patent literature publication "PACE 2 Specimen Collection Guide" (Gen Probe Incorporated Product Literature, 1996) has not been considered.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 13, 14, & 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Koch et al (US5578272). Regarding Claim 1, Koch et al teaches a cap comprising (Figures 6-10): an annular top wall having an opening formed therein (Column 3 lines 53-67); and a generally conical inner wall positioned

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beneath the opening and interrelated to the top wall (Figure 10), wherein the inner wall includes a plurality of radially extended striations (Figure 10 Item Numbers 94 & 95). Examiner takes the position that slots 94 and 95, which are made by a blade, define striations.

3. For Claim 2, Koch et al teaches the cap of Claim 1, further comprising an annular outer wall depending from the periphery of the top wall (Figure 10 Item number 83) and including means for fixedly associating the cap with an open end of a fluid-holding vessel (Figure 10 Item Number 89).

4. For Claim 3, Koch et al teaches the cap of Claim 1, wherein the inner wall depends from about the opening (Figure 10).

5. For Claim 4, Koch et al teaches the cap of Claim 1, wherein the top wall and the inner wall are joined to each other by a lower annular wall depending from about the opening (Figure 9). Examiner takes the position that the portion of the cap between the top wall (Item number 84) and inner wall (Item number 85) join the two portions of the cap together.

6. For Claim 5, Koch et al teaches the cap of Claim 1, further comprising an upper annular wall extending upwards from and generally perpendicular to the top wall (Figure 7). Examiner takes the position that the cap has an upper annular wall that forms the outside, or rim of the cap. This extends upward, and joins the top wall of the cap perpendicularly.

7. For Claim 6, Koch et al teaches the cap of Claim 5, further comprising a wick contained within the cap (Column 4 lines 5-6). Examiner takes the position that a wick is anything that may wipe off or "wick" the outside surface of the

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pipette used to puncture the seal. The metal sealing foil can define a wick, in its broadest reasonable interpretation.

8. For Claim 13, Koch et al teaches the cap of Claim 1, wherein the inner wall has an angle of from about 25° to 65° relative to the longitudinal axis of the cap (Column 3 lines 64-67).

9. For Claim 14, Koch et al teaches the cap of Claim 1, wherein each of the striations extends from a start-point at or near an apex of the inner wall (Figure 10 Item Numbers 94 & 95).

10. For Claim 25, Koch et al teaches the cap of Claim 1, wherein the cap is a molded plastic (Figures 7-10 and Column 3 line 53).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al in view of Percarpio (US4338764). Regarding Claim 6, Koch et al teaches the cap according to Claim 1. Koch et al does not teach the cap of Claim 5 further comprising a wick contained within the cap. Percarpio teaches this feature. Percarpio teaches the cap of Claim 5 further comprising a wick contained within the cap (Column 6 lines 26-31). Examiner takes the position that polytetrafluoroethylene defines a wick. It would have been obvious to one of ordinary skill at the the invention was made to modify Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36).

14. For Claim 7, Koch et al in combination with Percarpio, teach the cap according to Claim 6. Neither Koch et al, nor Percarpio, teach the cap of Claim 6 further comprising a wick positioned substantially above the top wall. It would have been obvious however, to one of ordinary skill at the time the invention was made to modify Koch et al with Percarpio to have positioned the wick substantially above the top wall because this would act as secondary barrier to the retention of biological fluids and biological material completely inside the container. This arrangement keeps contaminants from lodging onto the inner walls of the cap.

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15. For Claim 8, Koch et al in combination with Percarpio, teach the cap of Claim 6. Percarpio further teaches the cap of Claim 6, wherein the wick is a pile fabric. (Column 6 lines 26-31). Examiner takes the position that polytetrafluoroethylene defines a wick. It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Percarpio because according to Percarpio, this material is extremely resistant to hot and cold flow properties and resists attachment of fibrin and red blood cells (Column 6 lines 31-36).

16. For Claim 9, Koch et al in combination with Percarpio, teaches the cap according to Claim 6. Percarpio teaches the cap further comprises a seal affixed to the top surface of the upper annular wall (Figure 7 & Column 7 lines 23-30). It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Percarpio because according to Percarpio, this preferred embodiment (the seal and the diaphragm) is advantageous when the fluid concerned may be hazardous to personnel (Column 7 lines 35-40).

17. Claims 17-19 Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al, in view of Nelson (US795642). Regarding Claim 17, Koch et al teaches all of the claim limitations of Claim 1. Koch et al does not teach the cap of Claim 1 wherein the striations are formed on the inner surface, an outer surface, or both the inner and outer surfaces of the inner wall. Nelson teaches these features. Nelson teaches a stopper which may be used in combination with Koch et al, that would be considered part of the cap of Claim 1, wherein the striations are formed on the inner surface, an outer surface, or both

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the inner and outer surfaces of the inner wall (Figures 3 & 4 and First Page 1<sup>st</sup> Column last sentence to top of 2<sup>nd</sup> Column). It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Nelson because according to Nelson, this stopper would prevent the volatile liquid from escaping (First Page 1<sup>st</sup> Column 4<sup>th</sup> Paragraph). Examiner takes the position that striations and slits are equivalent.

18. For Claim 18, Koch et al in combination with Nelson, teach all of the claim limitations of Claim 17. Koch et al, in combination with Nelson further teaches the cap of Claim 17, wherein the inner wall has between 3 and 12 of the striations (Figure 4). It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Nelson because according to Nelson, this stopper would prevent the volatile liquid from escaping (First Page 1<sup>st</sup> Column 4<sup>th</sup> Paragraph). Examiner takes the position that striations and slits are equivalent.

19. For Claim 19, Koch et al in combination with Nelson, teach all of the claim limitations of Claim 1. Koch et al in combination with Nelson further teaches the claim limitations of Claim 1, wherein each of the striations comprises a groove in the inner wall (Figure 4). It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Nelson because according to Nelson, this stopper would prevent the volatile liquid from escaping (First Page 1<sup>st</sup> Column 4<sup>th</sup> Paragraph). Examiner takes the position that striations and slits are equivalent. Examiner also takes the position that a groove is created by the three slits as they meet at the central location.



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20. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al in view of Sandhage (US2906423). Koch et al teaches all of the claim limitations of Claim 1. Koch et al does not teach the cap of Claim 1, wherein an inner surface of the inner wall is at least partially coated with a lubricant. Sandhage teaches this feature. Sandhage teaches a cap puncturable by a polyethylene needle (Figures 1-3). Sandhage also teaches that a lubricant may be added to the surface of the cap (Column 2 lines 48-52). It would have been obvious to one of ordinary skill at the time the invention was made to modify Koch et al with Sandhage because according to Sandhage, addition of the lubricant to the stopper will allow for ease of insertion (of the needle) and the lubricant tends to fill up the cut slit thereby preventing the entry of contaminating microorganisms and also lubricating the entry of the polyethylene needle through the conical well into the interior of the bottle (column 2 lines 52-58)

### ***Double Patenting***

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-20, & 23-38 of U.S. Patent No. 676396 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

23. For Claim 1, A cap comprising: an annular top wall having an opening formed therein; and a generally conical inner wall positioned beneath the opening and interrelated to the top wall, wherein the inner wall includes a plurality of radially extending striations (Claim 1).

For Claim 2, The cap of claim 1 further comprising an annular outer wall depending from the periphery of the top wall and including means for fixedly associating the cap with an open end of a fluid-holding vessel (Claim 3).

For Claim 3, The cap of claim 1, wherein the inner wall depends from about the opening (Claim 23).

For Claim 4, The cap of claim 1, wherein the top wall and the inner wall are joined to each other by a lower annular wall depending from about the opening (Claims 30 & 34).

For Claim 5, The cap of claim 1 further comprising an upper annular wall extending upward from and generally perpendicular to the top wall (Claim 30).

For Claim 6, The cap of claim 5 further comprising a wick contained within the cap (Claim 8).

For Claim 7, The cap of claim 6, wherein the wick is positioned substantially above the top wall (Claim 32).

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For Claim 8, The cap of claim 6, wherein the wick is a pile fabric (Claims 30 and 31).

For Claim 9, The cap of claim 6 further comprising a seal affixed to a top surface of the upper annular wall (Claims 30-32).

For Claim 10, The cap of claim 6, wherein the combined force needed to penetrate the wick and the inner wall with a plastic pipette tip is less than about 10 pounds force (Claims 30 & 36).

For Claim 11, The cap of claim 6, wherein the combined force needed to penetrate the wick and the inner wall with a plastic pipette tip is less than about 7 pounds force (Claims 30 & 37).

For Claim 12, The cap of claim 6, wherein the combined force needed to penetrate the wick and the inner wall with a plastic pipette tip is less than about 4.5 pounds force (Claims & 38).

For Claim 13, The cap of claim 1, wherein the inner wall has an angle of from about 25 ° to about 65 ° relative to the longitudinal axis of the cap (Claim 11).

For Claim 14, The cap of claim 1, wherein each of the striations extends from a start-point at or near an apex of the inner wall (Claim 30).

For Claim 15, The cap of claim 1, wherein the thickness ratio between non-striated and striated portions of the inner wall is in the range of about 10:1 to about 1.25:1 (Claim 14).

For Claim 16, The cap of claim 1, wherein the average thickness of striated portions of the inner wall is between about 0.002 inches and about 0.008 inches, and wherein the average thickness of non-striated portions of the inner wall is between about 0.01 inches and about 0.02 inches (Claim 15).

For Claim 17, The cap of claim 1, wherein the striations are formed on an inner surface, an outer surface or both the inner and outer surfaces of the inner wall (Claim 17).

For Claim 18, The cap of claim 17, wherein the inner wall has between 3 and 12 of the striations (Claim 16).

For Claim 19, The cap of claim 1, wherein each of the striations comprises a groove in the inner wall (Claim 35).

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For Claim 20, The cap of claim 1 further comprising one or more radially extending ribs formed on an inner surface of the inner wall, each rib being positioned between a pair of adjacent striations (Claim 19).

For Claim 21, The cap of claim 1, wherein an inner surface of the inner wall is at least partially coated with a lubricant (Claim 20).

For Claim 22. The cap of claim 1, wherein the force needed to penetrate the inner wall with a plastic pipette tip is less than about 8 pounds force (Claim 37).

For Claim 23. The cap of claim 1, wherein the force needed to penetrate the inner wall with a plastic pipette tip is less than about 6 pounds force (Claim 38).

For Claim 24, The cap of claim 1, wherein the force needed to penetrate the inner wall with a plastic pipette tip is less than about 4 pounds force (Claim 38).

For Claim 25, The cap of claim 1, wherein the cap is a molded plastic (Claim 10).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

  
WALTER D. GRIFFIN  
SUPERVISORY PATENT EXAMINER

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/142004,  
12/09/2005,05/09/2007,.